Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-7 are pending in the application, with claim 1 being the independent claim. Claim 1 is amended. Support for this amendment can be found, *inter alia*, at page 4, line 4. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 112

Claims 1, 8 and 9 were rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Applicant points out that claims 8 and 9 are cancelled. Applicant respectfully traverses this rejection as it may be applied to the pending claims.

The Office Action stated that

> [a] therapeutic can be any product useful for treating a disease or disorder. Such products can be those that elicit effects other than an anti-self immune response. See e.g., Levinson. Looking to the claimed method, the applicant appears to be identifying not therapeutics in general, but only those that induce such a specific anti-self response in the host cell organism. As such, what is being claimed is not a method of identifying potential therapeutics generally, but potential vaccines to the infectious diseases.

Paper No. 15, page 3.

Applicant has amended claim 1, from which claims 2-7 depend, to recite a "method of screening for *potential vaccine targets for infectious diseases*" (emphasis added). Thus, the claims are not directed to a method for identifying therapeutics in general, but an assay for screening for gene products that may be useful as vaccine targets for treating or preventing infectious diseases. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 1-7 were rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Applicant respectfully traverses this rejection.

The Office Action stated that

> [t]he art surrounding the claimed invention not only provides little guidance to one intending to practice the claimed method, but it also fails to provide any indication that the claimed method would be capable of identifying therapeutics for infectious diseases. Further, the specification provided in support of the claims neither provides examples of such gene products, not [sic] any guidance as to what products are likely to be effective immunogenic therapeutics against infection. Further, one skilled in the art wishing to practice the invention is faced not only by this lack of guidance in the art and the specification, but also by a large number of potential therapeutics for a large number of infectious diseases. In view of the breadth of the claims, the lack of guidance, and the lack of any indication that any therapeutics according to the claimed invention are present to be found, the examiner finds that the applicant has not provided sufficient information such that one skilled in the art would be able to practice the claimed invention without undue experimentation.

Paper No. 15, page 7.

The large number of infectious diseases is precisely why the present invention is so useful. The claimed method can be used to screen for possible vaccine targets for any infectious disease. That is not to say the every infectious disease will induce differential

expression of an immunogen. However, the present method is a tool for identifying whether or not such an immunogen exists for a particular disease.

The present method is useful for identifying, as a first step, gene products which may be potential vaccine targets. The claimed method involves (1) identifying differentially expressed gene products and (2) screening these differentially expressed products for immunogenicity. Applicant provides ample guidance for practicing both steps of the claimed method. For example, methods of determining differential expression described in the specification include subtractive hybridization, representational difference analysis, and through the use of microarrays. *See* specification, page 10, lines 3-23. Methods of screening for immunogenicity described in the specification include stimulation of primary T cell responses *in vitro*, chromium release assays, *in vivo* immunoglobulin class switching, and determination of antibody production. *See* specification, page 11, line 27 to page 13, line 16. These and other methods for determining differential expression and screening for immunogenicity are routine and well known in the art.

Additionally, the specification states that

> [h]ost gene products . . . that are shown to be overexpressed by a factor of 9 or greater in infected cells as compared to uninfected cells are the most likely to be immunogenics. Optionally, relative gene expression is then determined in a broad panel of normal tissues. It is expected that immune tolerance will be induced to gene products expressed at relatively high levels in any normal tissue. Such gene products are excluded from further analysis.

Specification, page 4, lines 13-19. Thus, the specification does provide guidance as to which types of gene products would most likely be immunogenic and thus suitable vaccine targets.

The specification states that "[t]his method of vaccine development is broadly applicable to any infectious agent but especially to infectious agents that, like HIV, replicate

or mutate rapidly, for example, hepatitis C virus and many RNA viruses." Specification, page 8, lines 9-11. Thus, the specification also provides guidance regarding the infectious disease targets.

Applicant believes that claims 1-7 meet the enablement requirement. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 1-7 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Applicant respectfully traverses this rejection.

The Office Action stated

> while it is clear that immunogenicity generally requires that the gene product elicit an immune response against itself, it is unclear whether this immunogenicity may be in any organism, or if the gene product must be immunogenic in the organism in which the host cell is naturally found. In short, it is unclear from the claims whether the immunogenicity of a gene product is measured by assaying for a specific immune response against the product in the native organism of the host cell, or if the immunogenicity is measured in an organism other than the host cell native organism.
>
> The second reason that the claims are found indefinite is that the relationship between the potential therapeutics and the immunogenic host cell gene products that are differentially expressed is unclear.

Paper No. 15, page 9.

Applicant has amended claim 1, from which claims 2-7 depend, to recite that the "gene products which are immunogenic in said host are potential vaccine targets for infectious disease during which such upregulation or expression occurs." This amendment clarifies that the gene products are screened for the ability to induce an immune response in the native host and clarifies the relationship between the potential vaccine target and the host cell gene product. Applicant points out that immunogenicity may be screened for in the host

organism itself or a representative *in vitro* or *in vivo* model. Numerous ways of screening for immunogenicity are disclosed in the specification at pages 11-15 and are well known in the art.

Applicant believes that the claims satisfy the definiteness requirement. Accordingly, withdrawal of this rejection is respectfully requested.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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